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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,746	04/03/2001	Hans J. Hansen	018733-1015	1224

7590

10/30/2002

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/30/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

823,746

Applicant(s)

HANSEN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ✓ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-65 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-65 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-47, drawn to in vivo methods of treating or imaging diseased tissues involving administration of a bispecific antibody and a targetable conjugate comprising HSG hapten moieties, classified in class 424, subclasses 1.49+, 9.1+ and 136.1+.
- II. Claims 48-52 and 57-65, drawn to in vivo methods of treating or imagining target cells involving administration of a bispecific antibody and a targetable conjugate, classified in class 424, subclass 1.49.
- III. , Claims 53-54, drawn to targetable conjugates and kits containing such, classified in class 424, subclasses 1.49+, 9.1+ and 136.1; class 435, subclass 7.1+; class 514, subclass 2+; and class 530, subclass 328+.
- IV. Claims 55-56, drawn to methods of screening for a targetable conjugate, classified in class 424, subclass 9.1+ as well as class 435, subclass 7.1+.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Groups I and II have no clear relationship because the claims of Group I require that one arm of the bispecific antibody bind to the MSG moiety of a targetable conjugate, while the

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claims of Group II do not require that the one arm of the bispecific antibody bind to any particular moiety of the conjugate.

Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the conjugates of Group III, as well as the kit components of Group III, could be used to conduct an immunoassay --e.g. an immunoassay employing a hapten linked to a chelated radiolable, an immunoassay employing bispecific haptens as a linking moiety.

Inventions I (or II) and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the screening method of Group IV bears no clear relationship to Group I (or (+II)) because the targetable conjugates that are screened for in the method of Group IV have no particularly recited structure. Also the methods of Groups I (or-II) and IV have no common steps and achieve different ends. As such they are not capable of practice together.

If one of Groups I-III are elected, then the following election of species is required.

Claims 1-54 and 57-65 are generic to a plurality of disclosed patentably distinct species comprising the targetable conjugates listed in claims 48, 52-54, 57 and 61-63. Assuming that

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these species would be useable in Group I, applicant is required to elect one of these, or a different disclosed species, for the examination of Group I. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The election of species requirement is considered proper, since the structures of species (a)-(e) recited in claims 48, 52-54, 57 and 61-63 differ from each other in terms of sequence and/or the nature of moieties shown at the left hand end thereof.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Mon.-Thu. from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3704.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

October 7, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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